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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,753

05/13/2005

Pandurang Balwant Deshpande

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06/28/2006

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/532,753	DESHPANDE ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Golzález is noted but is not prior art to claim 9 because claim 9 is entitled to the 2/26/2003 priority date.

Claims 9 is rejected under 35 U.S.C. 102(b) as being anticipated by 6878827, 6350869, and 4559334/4935507.

In 6878827, note publication date of 6/13/2002. See reference example 1-(3). The reference is silent on whether the material is amorphous or whether it is a monohydrate.

In 6350869, see example 2, the monohydrate. The reference is silent on whether the material is amorphous.

In 4559334, see Examples 14 and 16, material which 4935507 says is "crystalline like amorphous product" (column 1, lines 27-28) meaning "an amorphous material" which is "not a crystalline product" but what presumably only looked like a crystalline product. Thus, 4935507 is cited as a supplemental reference to explain the nature of the material in 4559334.

In summary, one reference is a monohydrate, but silent on amorphous, one reference is amorphous, but silent on monohydrate, and one reference is silent on both.

MPEP 2112 states:

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**“SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE
DISCOVERY OF A NEW PROPERTY**

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).”

In this case, the “unknown property” is the particular form (amorphous form, form of a hydrate, or both). This is unknown because the reference is silent on this property.

MPEP 2112 goes on to state:

“A REJECTION UNDER 35 U.S.C. 102/103 CAN BE MADE WHEN THE PRIOR ART PRODUCT SEEMS TO BE IDENTICAL EXCEPT THAT THE PRIOR ART IS SILENT AS TO AN INHERENT CHARACTERISTIC

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection.”

Again, the “CHARACTERISTIC” which the prior art is silent on is the particular form.

This is not an ordinary inherency situation where it is not explicitly stated what the product actually is. Here the reference explicitly teaches exactly what the compound is. The only difference is a characteristic about which the reference happens to be silent. See also Ex parte Anderson, 21 USPQ 2nd 1241 at 1251, discussion of Rejection E. There, the decision states, “There is ample precedent for shifting the burden to an applicant to reproduce a prior art product whose final structure or properties are, at least, in part

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determined by the precise process used in its manufacture.” (page 1253). The “properties” branch of that statement applies here.

It is well settled that the PTO can require an applicant to establish that a prior art product does not necessarily possess the characteristics of the claimed product when the prior art and claimed products are identical or substantially identical. An applicant's burden under these circumstances was described in *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, or ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products (footnote omitted).

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by 6093814.

See example 4. Note that the initial acylation, using the tritylated acylating agent, is done using 44.0 mmol of the cephalosporin, and 88.0 mmol of the tributyl amine. Half of the amine will be consumed in the acylation process, meaning that some or all the remaining amine will be there to produce the salt, i.e. the tributyl ammonium salt. Thus, the material that exists just prior to adding the toluene sulfonic acid is in fact a solution of the salt of claim 14.

In addition, even if the compound were not in the salt form, but still the acid, that would anticipate for M=H.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 1079211 A1.

See operational example 1, which anticipates for M=H.

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Attention is called to 20060111566. The reference is not prior art. It appears to have the same salts as XIV here and the same process as claim 1.

Attention is called to 20060069079 and 20060029674. It is not clear whether this amorphous material is a monohydrate or not. The references are not prior art.

Attention is called to WO 2006010978 A1, example 7. It is not clear whether this amorphous material is a monohydrate or not. The reference is not prior art. Note WO 2006006040 A2, examples 4-6.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The variable X is not defined in claim 1.
2. The iminium choice in claim 2 has no counterion. This is impossible, as the molecule as a whole would not be neutral.
3. The first two choices for X in claim 2 are not moieties but are molecules themselves, and thus cannot be used.
4. All of the claim 3 choices except the first 5 are not ions at all but free molecules.
5. Regarding claim 4, 6, and 12 the phrase "and the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by

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"and the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

6. In claims 5-6, and 12 water is not an organic solvent. It needs to be removed for the list of choices.
7. The variable M is not defined in claim 10.

Claim Objections

Claim 9 needs to end with a period.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark L. Berch

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A handwritten signature in black ink, appearing to read "Mark Ben". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

**Primary Examiner
Art Unit 1624**

6/23/2006